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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,496	01/25/2002	David Leslie Mcneight	P67280US0	6657

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,496	MCNEIGHT, DAVID LESLIE	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-15 and 17-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-15, 17-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's amendment and request for extension of time, both filed 09/16/2004.

Claim 16 has been canceled and claims 17-22 have been added.

Claims 1, 4-15, and 17-22 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/16/2004 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 4-6, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB '906 in view of US 5,830,463 ('463).

GB '906 discloses a controlled release composition of active agents include nicotine provided in controlled release transdermal or oral devices, such devices read on the solid carrier of claim 5 and the patch of claim 16 (abstract; page 2, lines 69-75; page 5, lines 8-11, 18-19). The active agent is contained in plurality of microcapsules that distributed throughout the delivery device, and delivered continuously from the microcapsules to the skin or mucosa (page 2, lines 83-94). The active agent, i.e. nicotine, is administered from a suitable device in any convenient and appropriate form (page 3, lines 3-5). The solid active agent is delivered with a solvent, i.e. diluent (page 3, lines 5-10). The release of the active agent upon contact of the microcapsules with a nicotine solvent, as well as the limitation of claim 2 are related to the intended mechanism of action upon use of the delivery system, and not to the delivery system *per se,* and the mechanism of action of the encapsulated nicotine is inherent in the encapsulated nicotine of the prior art.

GB '906, however, does not teach that the microcapsules comprise yeast cells or the system comprising mixture of cells charged with nicotine and diluent-empty cells and the amount of loading of the nicotine into the microcapsules.

The amount of loading of the microcapsules with nicotine does not impart patentability to the claims, absent evidence to the contrary.

US '463 teaches yeast vehicle used for drug delivery (abstract). The yeast cells are safe and do not cause significant side effects (col.4, line 57; col.5, lines 35-36). The yeast vehicle carries the drug within the yeast periplasm, i.e. the drug inside the yeast cell that encapsulates the drug, or the yeast cell carries the drug on the membrane, i.e. the yeast cell itself is empty, and combination thereof (col.5, lines 1-4; col.6, lines 14-36). The yeast delivery vehicle is used for solid oral or transdermal controlled release formulations (col.18, lines 5-6, 24-25, 54-55, 63-66; col.19, lines 1-3).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to obtain a controlled release delivery system comprising encapsulated nicotine as taught by GB '906, and replace microcapsules that encapsulate the nicotine and the solvent by the yeast cells as taught by US '463, motivated by the teaching of US '463 that the yeast cells are safe and do not cause significant side effects, with reasonable expectation of having a delivery system comprising encapsulated nicotine with the capsules comprising yeast cells that deliver nicotine safely at controlled release rate to the subject in need with minimal side effects.

4. Claims 1, 4-6, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '334 in view of US '463.

US '334 discloses a nicotine containing dosage form for controlled release of nicotine comprising microencapsulated nicotine within a barrier capable of releasing the nicotine for transmucosal administration, the barrier reads on the solid carrier of claim 5 (abstract; col.9, lines 37-45; col.10, lines 8-10). The release of the active agent upon

contact of the microcapsules with a nicotine solvent, as well as the limitation of claim 2 are related to the intended mechanism of action upon use of the delivery system, and not to the delivery system *per se,* and the mechanism of action of the encapsulated nicotine is inherent in the encapsulated nicotine of the prior art.

US '334, however, the does not teach that the microcapsules comprises yeast cells or the system comprising mixture of cells charged with nicotine and diluent-empty cells and the amount of loading of the nicotine into the microcapsules.

The amount of loading of the microcapsules with nicotine does not impart patentability to the claims, absent evidence to the contrary.

US '463 teaches yeast vehicle used for drug delivery (abstract). The yeast cells are safe and do not cause significant side effects (col.4, line 57; col.5, lines 35-36). The yeast vehicle carries the drug within the yeast periplasm, i.e. the drug inside the yeast cell that encapsulates the drug, or the yeast cell carries the drug on the membrane, i.e. the yeast cell itself is empty, and combination thereof (col.5, lines 1-4; col.6, lines 14-36). The yeast delivery vehicle is used for solid oral or transdermal controlled release formulations (col.18, lines 5-6, 24-25, 54-55, 63-66; col.19, lines 1-3).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to obtain a controlled release delivery system comprising encapsulated nicotine as taught by US '334, and replace the encapsulating material that encapsulate nicotine and the excipient by the yeast cells as taught by US '463, motivated by the teaching of US '463 that the yeast cells are safe and do not cause significant side effects, with reasonable expectation of having a delivery system

comprising encapsulated nicotine with the capsules comprising yeast cells that deliver nicotine safely at controlled release rate to the subject in need with minimal side effects.

5. Claims 6-9, 12-15, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB '906 in view of US '463 and further in view of US 5,733,574 ('574).

Claims 6-9, 20 and 21 recite the delivery system as lozenge comprising sugar; and the delivery system further comprising flavoring agent (claim 12) and vitamin (claim 14), and claims 13 and 15 recite that the flavoring agent and the vitamin are encapsulated.

GB '906 disclosed a controlled release composition of active agents include nicotine provided in controlled release transdermal or oral devices, such devices read on the solid carrier of claim 5 and the patch of claim 16 (abstract; page 2, lines 69-75; page 5, lines 8-11, 18-19). The active agent is contained in plurality of microcapsules that distributed throughout the delivery device, and delivered continuously from the microcapsules to the skin or mucosa (page 2, lines 83-94). The active agent, i.e. nicotine, is administered from a suitable device in any convenient and appropriate form (page 3, lines 3-5). The solid active agent is delivered with a solvent, i.e. diluent (page 3, lines 5-10).

GB '906 does not teach the delivery system as a lozenge comprising sugar as claimed in claims 6-9, or the delivery system comprises flavoring agent and

supplemental vitamin or the encapsulation of the flavoring agent and the vitamin as claimed in claims 12-15.

US '574 teaches a saliva soluble delivery unit for oral use that provides a controlled release of nicotine in the form of lozenge (abstract; col.3, lines 10-16; col.9, lines 34-35, 44, 48). The saliva soluble delivery unites comprising nicotine, sugar, flavoring agent, and vitamins because smokers usually loose vitamins and some vitamins act as stabilizing agents (col.7, lines 58-62; col.8, lines 31-34, 51-64). The reference teaches that the nicotine delivery unit provides a nicotine dose corresponding to the stimulation of nicotine obtained by smoking a cigarette (col.3, lines 30-34; col.5, lines 31-33). The reference also disclosed that the flavor could be tobacco flavor that is provided from smokeless nicotine and does not contribute significantly to the level of nicotine (col.3, lines 34-36; col.8, lines 31-34).

One having ordinary skill in the art would have encapsulate the flavoring agents and the vitamins for the same reason the active ingredient has been capsulated by GB '906, i.e. providing continuous controlled release of the encapsulated agents.

In order to have the delivery of nicotine that provide a particular blood concentration in a certain period of time, one having ordinary skill in the art would have been expected to adjust the oral delivery unit regarding its size, solubility and charge of nicotine to obtain the desired blood concentration in the desired time. Applicant is not claiming any particular amount of nicotine in the cigarette nor the desired blood level that needed to be achieved.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to obtain a controlled release delivery system comprising encapsulated nicotine as taught by GB '906 in the form of lozenge that comprises sugar vitamins and flavoring agent as disclosed by US '574, motivated by the teaching of US '574 that the delivery units in form of lozenge provide nicotine dose corresponding to the stimulation of nicotine obtained by smoking a cigarette, as desired by applicant, and also one having ordinary skill in the art would have been motivated to add flavoring agent and vitamin to the nicotine lozenge motivated by the teachings of US '574 that the flavor could be tobacco flavor that is provided from smokeless nicotine and does not contribute significantly to the level of nicotine and that smokers usually loose vitamins and some vitamins act as stabilizing agents, with reasonable expectation of having a lozenge that provides nicotine equivalent to that delivered by cigarette in a controlled release manner and meanwhile deliver vitamin supplement all in one delivery system that have an acceptable flavor.

6. Claims 6, 7, 9, 11, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB '906 in view of US '463 and further in view of US 6,358,060 ('060).

Claims 6, 7, 9, 20 and 21 recite the delivery system as a lozenge, and claim 11 recites the delivery system as chewing gum.

GB '906 disclosed a controlled release composition of active agents include nicotine provided in controlled release transdermal or oral devices, such devices read

on the solid carrier of claim 5 and the patch of claim 16 (abstract; page 2, lines 69-75; page 5, lines 8-11, 18-19). The active agent is contained in plurality of microcapsules that distributed throughout the delivery device, and delivered continuously from the microcapsules to the skin or mucosa (page 2, lines 83-94). The active agent, i.e. nicotine, is administered from a suitable device in any convenient and appropriate form (page 3, lines 3-5). The solid active agent is delivered with a solvent, i.e. diluent (page 3, lines 5-10).

GB '906 does not each the delivery system as a lozenge as claimed in claims 6, 7, and 9 or chewing gum as claimed in claim 11.

US '060 teaches a delivery system in the form of lozenge or chewing gum to deliver encapsulated nicotine, wherein the delivery system is convenient, reliable, practical and painless (abstract; col.7, lines 10-12, 56-59; col.10, lines 46-47). The delivery system provides amount of nicotine that is absorbed into the blood stream within 5 minutes and provides concentration sufficient to provide craving relief and for 20 minutes (col.8, lines 2-10; col.9, lines 49-61).

In order to have the delivery of nicotine that provide a particular blood concentration in a certain period of time, one having ordinary skill in the art would have been expected to adjust the oral delivery unit regarding its size, solubility and charge of nicotine to obtain the desired blood concentration in the desired time. Applicant is not claiming any particular amount of nicotine in the cigarette nor the desired blood level that needed to be achieved.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the nicotine oral delivery system of GB '906 in the form of lozenge or chewing gum as disclosed by US '060, motivated by the teaching of US '060 that lozenge and chewing gum are convenient, reliable, practical and painless method to administer nicotine, and lozenge and chewing gums provide amount of nicotine that is absorbed into the blood stream within 5 minutes and provides concentration sufficient to provide craving relief and for 20 minutes, with reasonable expectation of having a lozenge or chewing gum to deliver nicotine in a controlled release manner and also provide craving relief for sufficient time to the subject in need.

7. Claims 10 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB '906 in view of US '463 and US '574 as applied to claims 6-9, 12-15 above or over GB '906 in view of US '463 and US '060 as applied to claims 6,7, 9, and 11 above, and further in view of GB 2 299 756 ('756).

Claims 10 and 22 recite the lozenge having 5-20 cm length with preferential snapping positions.

The teachings of GB '906 in view of US '463 and US '574 and GB '906 in view of US '463 and US '060 are discussed above. However, the references in combination do not teach the size or shape of the lozenge delivery system.

GB '756 teaches product in the form of pastille for oral ingestion containing nicotine and flavoring agent, vitamin, and sugar (abstract; page 1, last paragraph; claims 5, 6, 9, 16, 17). The pastille may be of such size and contain as much nicotine

as will correspond to the time taken to smoke a cigarette and the amount of nicotine absorbed by the tissue of the buccal cavity during such time (page 3, second full paragraph). The product in the form of rod or bar-like and has zones of weakness allowing it to be broken into smaller pieces, claim 10 (page 3, second full paragraph; claim 14).

The reference implies that the size of the delivery unit is adjustable to such size and contain as much nicotine as will correspond to the time taken to smoke a cigarette and the amount of nicotine absorbed by the tissue of the buccal cavity during such time. Thus, the size of the lozenge as a whole as claimed by applicant does not impart patentability to the claim because what is important is the size and amount of the nicotine in the snapped part that administer the nicotine, and also we do not know how much nicotine in the claimed size or how much blood concentration needed to be achieved, absent evident to the contrary.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver the delivery system in the form of lozenge as taught by GB '906 in view of any of US '574 or US '060 and select the bar-like shape with zones of weakness to break the lozenge as taught by GB '756, motivated by the teaching of GB '756 that the breakable system ease the accommodation in the mouth while providing the requisite dosage of nicotine over the appropriate time, with reasonable expectation of providing lozenge with preferential snapping positions that accommodate in the mouth and provide the sufficient nicotine level in the blood for the required period of time as a successful smoking substitute.

Response to Arguments

8. Applicant's arguments filed 09/16/2004 have been fully considered but they are not persuasive. The main gist of applicant's argument against the rejection of the claims over GB '906 by arguing that the reference teaches release of the encapsulated agent through an orifice. US '463 is that the references do not teach the use of yeast cells to encapsulate the active agent, but active agent are present on the yeast surface, and does not teach nicotine. US '334 does not each the encapsulation with yeast, but coating of nicotine droplets. No motivation to combine the cited references.

In response to the above arguments, the examiner position is that the claims are directed to a product and all the elements of the product are disclosed by combination of the references because both of the primary references teach the encapsulation of nicotine, but not specifically encapsulation within yeast cells. The secondary reference teaches the encapsulation of drugs in yeast cells because yeast cells are safe and do not cause significant side effects. The release of encapsulated active agent from the capsule through an orifice or by dissociation, or diffusion etc., does not impart patentability to the product claims. Therefore the claims are obvious over GB '906 in view of US '463. Regarding US '433, the reference clearly teaches microencapsulation of nicotine, col.9, line 40, col.10, lines 9, 59, 63. In any event, coating reads on encapsulation because coating means "a layer covering a material", and encapsulation means "to encase in", WEBESTER'S II dictionary. Regarding US '463, at col.5, lines 1-

5, and col.6, lines 35 and 36, the reference teaches that the active agents can be carried within or inside the yeast cell. Thus, it would have been obvious to one having ordinary skill in the art to encapsulate drugs to be delivered to patient in a yeast cells based on the safety of the delivered formulation. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the teaching of US '436 that yeast cells are safe and do not cause serious side effects would motivate encapsulating nicotine into yeast cells.

In considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. Furthermore, one cannot show nonobviousness by attacking the references individually where the rejections are based on combination of references. *See In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615